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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,961	09/18/2001	Minter H. Dopson	01-2224	8520
27530	7590	11/05/2007	EXAMINER	
NELSON MULLINS RILEY & SCARBOROUGH, LLP			SCHWADRON, RONALD B	
1320 MAIN STREET, 17TH FLOOR			ART UNIT	
COLUMBIA, SC 29201			PAPER NUMBER	
			1644	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/954,961	DOPSON, MINTER H.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9 and 23-34 is/are pending in the application.
 - 4a) Of the above claim(s) 1-9,24,25 and 32 is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 23,26-33,33,34 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date ____.	6) <input type="checkbox"/> Other: ____.

1. Applicant's election of method using fertilized eggs in the reply filed on 8/13/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Newly submitted claim 32 is directed to a species that is distinct from the species originally elected in response to the election requirement of 12/22/05 and wherein said species is distinct in that it uses different ingredients as per the species enunciated in said election requirement. Since applicant has received an action on the merits for the originally presented species, this species has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 32 is withdrawn from consideration as being directed to a non-elected species. See 37 CFR 1.142(b) and MPEP § 821.03.
3. Regarding applicants comments, claim 23 is interpreted as being generic to the use of fertilized or unfertilized eggs.
4. Claims 23,26-31,33,34 are under consideration.
5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 is indefinite in the recitation of "raw egg yolk" because it is unclear as to what said term means or encompasses. Said term is not defined in the specification. Whilst said term could appear to encompass uncooked, it is unclear as to what other manipulations would be excluded by the term "raw" other than uncooked.
7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 23,26-28,31,33,34 are rejected under 35 U.S.C. 102(b) as being anticipated by Tokoro (US Patent 5,080,895). Applicants arguments have been considered and deemed not persuasive.

Tokoro teaches a method of making transfer factor specific for a pathogen wherein the transfer factor includes the particular transfer factor recited in the claims (because the method of Tokoro uses a filtration step that recovers transfer factor less than 10,000 mw)(see abstract and columns 5-7 and Example II). The specification discloses that transfer factor is less than 10,000 mw (see specification, page 2, last paragraph). The transfer factor is purified from the eggs of an immunized hen (see Example 2). Thus, the transfer factor containing eggs are first collected from the immunized hen. The hens (female birds of the family Phasianidae as per the definition of said term in the specification, page 10, second paragraph) can be immunized with a specific virus to produce an antiviral transfer factor (see column 4, penultimate paragraph). Tokoro discloses that the egg whites (aka albumen) and yolks are mixed with PBS (which contains water), the mixture is treated to remove cell and cell debris (centrifugation) and the supernatant was recovered (see Example II). At least some portion of the fluid would be lost to evaporation. The method uses a preparation that contains “raw egg yolk” (if said term is interpreted as simply meaning uncooked) (see Example II). Tokoro teaches use of eggs in the aforesaid method. Chicken eggs can be unfertilized or fertilized. Thus the routine would at once envisaged that eggs encompassed fertilized eggs (eg. one of the two known members of the genus of eggs aka fertilized or unfertilized) because fertilized and unfertilized eggs were known in the art and the genus only consisted of two members. See *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978).

Applicants arguments have been considered and deemed not persuasive.

Tokoro teaches a method of making transfer factor specific for a pathogen wherein the transfer factor includes the particular transfer factor recited in the claims (because the method of Tokoro uses a filtration step that recovers transfer factor less than 10,000 mw)(see abstract and columns 5-7 and Example II). The specification discloses that transfer factor is less than 10,000 mw (see specification, page 2, last paragraph). The transfer factor is purified from the eggs of an immunized hen (see Example 2).

Regarding applicants comments about "purified", said term is not defined in the specification and would encompass any purification step. The method of Tokoro uses a purification step. Regarding applicants comments about what purified means, the MPEP section

716.01(c) [R-2] states:

>II. ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

The transfer factor containing eggs are first collected from the immunized hen. The hens (female birds of the family Phasianidae as per the definition of said term in the specification, page 10, second paragraph) can be immunized with a specific virus to produce an antiviral transfer factor (see column 4, penultimate paragraph). Tokoro discloses that the egg whites (aka albumen) and yolks are mixed with PBS (which contains water), the mixture is treated to remove cell and cell debris (centrifugation) and the supernatant was recovered (see Example II). At least some portion of the fluid would be lost to evaporation. The method uses a preparation that contains "raw egg yolk".

Regarding applicants comments, the method of Tokoro results in a product that contains transfer factor because Tokoro uses a filtration step that recovers transfer factor less than 10,000 mw(see abstract and columns 5-7 and Example II). The specification discloses that transfer factor is less than 10,000 mw (see specification, page 2, last paragraph). *The name used to describe the crude preparation obtained by the method of Tokoro is irrelevant because it contains all molecules less than 10,000 mw, including transfer factor. The method disclosed by Tokoro in Example II discloses*

steps that the specification discloses would yield a preparation containing transfer factor (centrifugation, filtration and precipitation (see page 14)). Regarding the Dunnick et al. reference to which applicant refers, as per above the name used to describe the crude preparation obtained by the method of Tokoro is irrelevant because it contains all molecules less than 10,000 mw, including transfer factor. In addition, applicants comments indicate that transfer-like factor cannot transfer immunity. *However, the factor disclosed by Tokoro can transfer immunity (see column 4, first complete paragraph) and therefore appears to be a "transfer factor" (regardless of the name used by Tokoro).* There is no disclosure in the Tokoro patent that their transfer factor has any relation to the molecule disclosed by Dunnick et al. Furthermore, the Dunnick et al. reference does not even disclose that the molecule they have isolated is even found in chickens (it refers to guinea pigs). In addition, the molecule disclosed in Dunnick et al. is prepared using a procedure that is totally different from that used by Tokoro .

Regarding applicants comments about claim 33, Tokoro teaches use of eggs in the aforesaid method. Chicken eggs can be unfertilized or fertilized. Thus the routineer would at once envisaged that eggs encompassed fertilized eggs (eg. one of the two known members of the genus of eggs aka (fertilized or unfertilized)) because fertilized and unfertilized eggs were known in the art and the genus of eggs only consisted of two members. See *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 23,26-31,33,34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokoro (US Patent 5,080,895) in view of Anderson et al. (US Patent 6,475,527). Applicants arguments have been considered and deemed not persuasive. Tokoro teaches a method of making transfer factor specific for a pathogen wherein the transfer factor includes the particular transfer factor recited in the claims (because the method of Tokoro uses a filtration step that recovers transfer factor less than 10,000 mw)(see abstract and columns 5-7 and Example II). The specification discloses that transfer factor is less than 10,000 mw (see specification, page 2, last paragraph). The transfer factor is purified from the eggs of an immunized hen (see Example 2). Thus, the transfer factor containing eggs are first collected from the immunized hen. The hens (female birds of the family Phasianidae as per the definition of said term in the specification, page 10, second paragraph) can be immunized with a specific virus to produce an antiviral transfer factor (see column 4, penultimate paragraph). Tokoro discloses that the egg whites (aka albumen) and yolks are mixed with PBS (which contains water), the mixture is treated to remove cell and cell debris (centrifugation) and the supernatant was recovered (see Example II). At least some portion of the fluid would be lost to evaporation. The method uses a preparation that contains "raw egg yolk". Tokoro does not disclose that the hens receive sodium chlorate. Anderson et al. disclose that fowl can be treated with sodium chlorate to reduce food borne enteric pathogens (see abstract, claim 19, column 2, last paragraph, continued on column 3 and column 3, first complete paragraph). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Tokoro teaches the claimed invention except that the hens receive sodium chlorate whilst Anderson et al. disclose that fowl can be treated with sodium chlorate to reduce food borne enteric pathogens (see abstract, claim 19, column 2, last paragraph, continued on column 3 and column 3, first complete paragraph). At least a portion of the administered sodium chlorate would end up in the egg. One of ordinary skill in the art at the time the invention was made would have been motivated to do the aforementioned because Anderson et al. disclose that fowl can be treated with sodium chlorate to reduce food borne enteric pathogens wherein enteric pathogens in animal food products are a problem (column 1, penultimate paragraph).

Applicants arguments are the same as addressed above. Anderson et al. disclose that fowl can be treated with sodium chlorate to reduce food borne enteric pathogens (see abstract, claim 19, column 2, last paragraph, continued on column 3 and column 3, first complete paragraph).

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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